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Proposed Registration Decision PRD2012-01

Sulphur

(publié aussi en français)

11 January 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2012-1E (print version)
H113-9/2012-1E-PDF (PDF version)

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Overview

Proposed Registration Decision for Sulphur

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Hollysul Technical Sulphur and Grotek Ascend Vaporized Sulphur, containing the technical grade active ingredient sulphur, to control powdery mildew caused by various pathogens on vegetables, small fruit, and ornamentals in greenhouses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Hollysul Technical Sulphur and Grotek Ascend Vaporized Sulphur.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g., children) as well as organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Product ct.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on sulphur, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on sulphur, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Sulphur?

Sulphur is the oldest known pesticide. It is a low cost, multi-site fungicide that is widely used to control powdery mildew on many crops. Sulphur is the active ingredient in Grotek Ascend Vaporized Sulphur. It is generally accepted that the efficacy of sulphur for powdery mildew control is related to contact and vapour activity. Sulphur inhibits germination of spores of the powdery mildew fungi, although the mode of action is uncertain. Sulphur vapour may be absorbed into lipids in spores and metabolism by the fungi may lead to hydrogen sulphide (H_2S) production and blocking of respiration.

Health Considerations

Can Approved Uses of Grotek Ascend Vaporized Sulphur Affect Human Health?

Grotek Ascend Vaporized Sulphur is unlikely to affect your health when the product is used according to the label directions.

Potential exposure to Grotek Ascend Vaporized Sulphur may occur when handling and applying the product or through the diet (food). When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Grotek Ascend Vaporized Sulphur consists of 99.9% elemental sulphur, a previously registered technical active ingredient. Sulphur is of low acute toxicity by the oral, dermal, and inhalation routes. Sulphur is also considered to be a mild skin irritant, moderately irritating to the eyes, and non-sensitizing.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use for Grotek Ascend Vaporized Sulphur is as a fungicide to be applied via vaporizers to greenhouse vegetables, small fruit, and ornamentals. This use should not result in additional exposure beyond currently registered food uses of sulphur. Vaporized sulphur is not expected to come into contact with any water supplies. Therefore, the use of Grotek Ascend Vaporized Sulphur is not expected to result in dietary risk from consuming food or drinking water.

Risks in Residential and Other Non-Occupational Environments

Risks to residential and other non-occupational environments are not of concern when Grotek Ascend Vaporized Sulphur is used according to label directions, which include protective measures.

Grotek Ascend Vaporized Sulphur is for use in commercial greenhouses. It is not intended for use in residential or non-occupational environments.

Sulphur vaporizers used for the application of Grotek Ascend Vaporized Sulphur are to be turned on only when greenhouses are closed to staff, the public and/or customers. Also, vaporizers are to be used only when greenhouses can be ventilated without exposing bystanders or occupants of adjacent structures to vaporized sulphur. Vaporizers are not to be used if a greenhouse shares a common wall, floor or ceiling with a building inhabited by livestock or humans. Therefore, the use of Grotek Ascend Vaporized Sulphur is not expected to result in any risks to bystanders from vaporized sulphur.

Occupational Risks From Handling Grotek Ascend Vaporized Sulphur

Occupational risks are not of concern when Grotek Ascend Vaporized Sulphur is used according to label directions, which include protective measures.

There is a potential for dermal and inhalation exposure to Grotek Ascend Vaporized Sulphur when filling the sulphur vaporizers, if workers enter the greenhouse during the vaporization process or when performing crop maintenance, harvesting or other activities after vaporization is complete. There is also a potential for inhalation exposure to sulphur dioxide if workers enter the greenhouse during the vaporization process.

The toxicity of sulphur is low by the dermal and inhalation routes of exposure. Workers filling and servicing sulphur vaporizers with Grotek Ascend Vaporized Sulphur would be exposed to similar or lesser amounts of sulphur compared to workers handling currently registered products containing sulphur. Workers filling and servicing sulphur vaporizers are also required to wear similar personal protective equipment (PPE) as workers handling currently registered products. According to the label instructions, sulphur vaporizers are to be operated by a timer or remote switch and greenhouse entrances should be locked and have warning signs during vaporization.

Also, workers are not to enter the greenhouse until vaporization is complete, the greenhouse is thoroughly ventilated, and the re-entry interval (24 hours) on the label has passed, unless the workers are wearing full protective clothing and a self-contained breathing apparatus. Because the application rates for Grotek Ascend Vaporized Sulphur are lower than application rates for currently registered products containing sulphur, the exposure of workers to sulphur when they are performing crop maintenance and harvesting activities is expected to be less than for currently registered products.

Sulphur dioxide can be formed if sulphur is (over-)heated beyond vaporization temperatures. The label for Grotek Ascend Vaporized Sulphur includes instructions for avoiding the formation of sulphur dioxide during the filling of the vaporizers. In addition, the estimated levels of sulphur dioxide formed during vaporization are less than occupational exposure limits included in provincial occupational health and safety regulations.

Therefore, the use of Grotek Ascend Vaporized Sulphur is not expected to result in increased risks from occupational exposures to vaporized sulphur or sulphur dioxide.

Environmental Considerations

What happens when Hollysul Technical Sulphur and Grotek Ascend Vaporized Sulphur is introduced into the environment?

Sulphur and the associated end-use product Grotek Ascend Vaporized Sulphur are to be used in the enclosed space of a greenhouse. The product is applied as a vapour and ultimately vented to the outside in a controlled manner once treatment is completed; the only contact sulphur will have with the environment is at the point of venting. The small amount of vapourized sulphur vented to the outside will dissipate rapidly in air upon release, and result in minimal environmental exposure to non-target organisms.

Value Considerations

What Is the Value of Grotek Ascend Vaporized Sulphur?

Sulphur, the active ingredient in Grotek Ascend Vaporized Sulphur, controls powdery mildew on vegetables, small fruits and ornamentals in greenhouse.

Grotek Ascend Vaporized Sulphur is applied using a sulphur vaporizer in greenhouses to control powdery mildew caused by various pathogens on greenhouse vegetables (tomato, pepper and eggplant), small fruit (strawberry), and greenhouse ornamentals (rose, gerbera, kalanchoe, begonia, hydrangea, snapdragon, African violet, chrysanthemum, phlox and dahlia). To apply the vaporized sulphur, elemental sulphur is loaded into a sulphur vaporizer and the device vaporizes a certain amount of sulphur per hour under a specific operating temperature. Other sulphur products applied as foliar spray or dust are currently registered for above mentioned crops and plants in greenhouses. Grotek Ascend Vaporized Sulphur may provide Canadian greenhouse growers an additional application method of sulphur to control powdery mildew in greenhouses.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Grotek Ascend Vaporized Sulphur to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements, "WARNING – EYE IRRITANT" and "CAUTION – SKIN IRRITANT" have been included on the principal display panel of the label for Grotek Ascend Vaporized Sulphur. The statements, "KEEP OUT OF REACH OF CHILDREN AND UNAUTHORIZED PERSONNEL. Do not inhale dust or vapour. Causes eye irritation and may irritate the skin. Do not get in eyes and avoid contact with the skin. Wear goggles or a face shield, a NIOSH-approved respirator, chemical resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots when filling, cleaning, and repairing sulphur vaporizers. Do not enter or allow workers to enter into treated areas until 24 hours after application unless wearing a self-contained breathing apparatus, goggles or a face shield, chemical resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots. Sulphur vaporizers should only be used at times when the greenhouse is closed to staff, public and/or customers. Vaporizers should only be used when a greenhouse can be ventilated without exposing bystanders or occupants of adjacent structures to vaporized sulphur. Vaporizers are not to be used if the greenhouse shares a common wall, floor or ceiling with a building inhabited by livestock or humans.", have been included in the Precautions section of the secondary display panel for Grotek Ascend Vaporized Sulphur.

Additional label precautionary statements for the vaporizers to prevent fires, spillage of molten sulphur, and the formation of sulphur dioxide include, "As device will get very hot, do not touch until cooled down. Do not enclose the vaporizer during operation or block any of the openings as this may cause a fire. Do not overfill the cup beyond 2 cm depth as this may cause the molten sulphur to boil over onto the hot element and cause a fire or gases that are toxic to plants and humans."

Environment

No mitigative measures are required for the registered use of Grotek Ascend Vaporized Sulphur.

Next Steps

Before making a final registration decision on sulphur, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on sulphur (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Sulphur

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Sulphur
Function	Fungicide, Acaricide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	sulfur
2. Chemical Abstracts Service (CAS)	sulfur
CAS number	7704-34-9
Molecular formula	S
Molecular weight	32.06
Structural formula	S
Purity of the active ingredient	99.9% minimum

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product – Hollysul Technical Sulphur

Property	Result
Colour and physical state	yellow powder
Odour	odourless to faint sulphurous odour
Melting range	112.8 – 119°C
Boiling point or range	444.6°C
Density	2.07 g/mL
Vapour pressure at 25°C	0.098 mPa
Ultraviolet (UV)-visible spectrum	* (nm) * (L mol^{-1} cm^{-1}) 220 1451 264 805 300 400
Solubility in water at 20°C	0.063 mg/L
Solubility in organic solvents at 20°C (g/100 mL)	Solvent Solubility Toluene 1.57 Dichloromethane 1.10 n-Heptane 0.18 Acetone 0.048

Property	Result	
n-Octanol-water partition coefficient (K_{ow})	pH 7.0	log K_{ow} 0.23
Dissociation constant (p*K*a)	No dissociation	
Stability (temperature, metal)	Stable at normal temperatures	

End-Use Product – Grotek Ascend Vaporized Sulphur

Property	Result
Colour	yellow
Odour	odourless to faint faint sulphurous odour
Physical state	powder
Formulation type	dust
Guarantee	99.9 %
Container material and description	plastic pouch or jar
Density	2.36
pH of 1% dispersion in water	no acidic or basic characteristics
Oxidizing or reducing action	does not contain oxidizing or reducing agents
Storage stability	stable under warehouse conditions
Corrosion characteristics	not corrosive when stored under warehouse conditions
Explodability	heavy dust can be explosive

1.3 Directions for Use

Grotek Ascend Vaporized Sulphur is a preventative fungicide used to control powdery mildew caused by various pathogens on vegetables, small fruit and ornamentals in greenhouses. To apply the vaporised sulphur, elemental sulphur is loaded into the sulphur vaporizer (100-200 g/unit) and the device is hung at least 0.5 m above the crop canopy in the greenhouse. The device runs at an operating temperature of 190°C and evaporates 0.3-0.4 g sulphur per hour. The proposed use rates are different dependent on the plants grown in the greenhouse. Typically one (1) vaporizer per 1,000 m^2 for tomato, pepper, eggplant and strawberry; one (1) vaporizer per 100 m^2 for rose; and one (1) vaporizer per 250-1,000 m^2 for other ornamentals, such as African violet, begonia, Chrysanthemum, dahlia, gerbera, hydrangea, kalanchoe, phlox and snapdragon. For all the intended uses, sulphur vaporizer operates two to seven nights weekly for one to eight hours per night.

1.4 Mode of Action

Sulphur belongs to the Group M2 class of fungicides. It is generally accepted that the efficacy of sulphur is related to contact and vapour activity. Sulphur inhibits germination of spores of the powdery mildew fungus, although the mode of action is uncertain. Sulphur vapour may be absorbed into lipids in spores and metabolism by the fungus may lead to hydrogen sulphide (H_2S) production and blocking of respiration.

Sulphur formulations differ substantially with respect to particle size. Particle size can affect persistence (degradation) and efficacy. Larger particles persist and vaporise over longer periods,

degrade at a lower rate and have lower efficacy. Smaller particles persist and vaporise over shorter periods, degrade at a higher rate and have relatively higher efficacy.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Hollysul Technical Sulphur have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

Sulphur, as a technical grade active ingredient, is currently registered as a fungicide, insecticide, acaricide, and rodenticide for use on terrestrial and greenhouse food crops, outdoor and greenhouse ornamentals, and vertebrate burrows. The proposed use pattern of Grotek Ascend Vaporized Sulphur (i.e., vaporized sulphur for use on greenhouse food (USC 5) and non-food (USC 6) crops) is considered a major new use for sulphur.

3.1 Toxicology Summary

Sulphur was the subject of a re-evaluation by the PMRA in 2004 which was summarized in the document, Proposed Acceptability for Continuing Registration, Sulphur (PACR2004-10). It was determined that sulphur was acceptable for continued registration provided that specific exposure mitigation measures were adopted and data requirements addressed. The PMRA re-evaluation was mainly based on information from the United States Environmental Protection Agency's Reregistration Eligibility Decision Document Sulfur.

Sulphur is of low acute toxicity by the oral, dermal, and inhalation routes. It is considered to be a mild skin irritant, moderately irritating to the eyes, and non-sensitizing. The end-use product, Grotek Ascend Vaporized Sulphur, contains no formulants of toxicological concern.

3.2 Occupational, Residential, and Bystander Exposure and Risk Assessment

There is a potential for dermal and inhalation exposure to the end-use product in occupational scenarios including filling and servicing sulphur vaporizers, during vaporization, and crop maintenance and harvesting tasks. However, due to the low toxicity of sulphur, the low application rates compared to currently registered sulphur containing end-use products, and the exposure mitigation measures on the label, there is no concern regarding occupational exposure to Grotek Ascend Vaporized Sulphur.

Precautions on the label include directions to not inhale dust or vapour, to not get the product in the eyes and avoid contact with the skin. Directions are also provided to prevent access to the greenhouse by workers, bystanders, and others during the vaporization process and until the re-entry interval is complete. Personal protective equipment required on the label when filling and servicing the vaporizers includes goggles or a face shield, a respirator, chemical resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots. If there is a need to access a greenhouse during vaporization, workers must use the same PPE described above along with a self-contained breathing apparatus.

In accordance with exposure mitigation measures outlined in PACR2004-10, the restricted entry interval (REI) required on the label for Grotek Ascend Vaporized Sulphur is 24 hours.

Grotek Ascend Vaporized Sulphur is for use in commercial greenhouses. It is not intended for use in residential or non-occupational environments. The label provides precautions for avoiding bystander or non-occupational exposure to vaporized sulphur including preventing use of sulphur vaporizers when greenhouses share common structures with buildings inhabited by livestock or humans and directions to only vent greenhouses treated with vaporized sulphur when exposure to bystanders or occupants of adjacent structures can be avoided.

Sulphur dioxide can be formed if sulphur is (over-)heated beyond vaporization temperatures. The label for Grotek Ascend Vaporized Sulphur includes instructions for avoiding the formation of sulphur dioxide and the estimated levels of sulphur dioxide formed during vaporization are less than provincial occupational exposure limits for the substance.

3.3 Food Residues Exposure Assessment

Sulphur is an essential component of plant and animal cells that is normally found in the diet. Sulphur was first registered as a pesticide in Canada in 1927. It has been used as a fungicide, insecticide and acaricide on commercial agricultural crops, greenhouse vegetable crops, and domestic ornamentals, fruits and vegetables. The PMRA re-evaluated sulphur in 2004 and accepted it for continued registration provided that specific mitigation measures and data requirements were addressed. The use of Grotek Ascend Vaporized Sulphur as a fungicide applied via vaporizers to greenhouse vegetables and fruit is not expected to result in any additional food residue exposure beyond currently registered food uses of sulphur.

Sulphur is a naturally occurring dietary constituent, no toxicological endpoints of concern have been established for it, no United States Environmental Protection Agency tolerance level or Canadian maximum residue limit (MRL) was established in the past, and the European Commission is discontinuing its existing MRLs for sulphur. Although the Food and Drugs Act prohibits the sale of adulterated food in Canada, foods containing sulphur are exempt from this prohibition. Therefore, it is not necessary to establish a Canadian MRL for sulphur.

The use of Grotek Ascend Vaporized Sulphur is limited to greenhouses and the label includes instructions for avoiding releases to water or drainage. Consequently, vaporized sulphur is not expected to come into contact with any water supplies.

4.0 Incident Reports

Since 26 April 2007 registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents from Canada were searched and reviewed for sulphur.

As of 5 August 2011 there have been seven human incidents reported for products containing sulphur in Canada which were classified as minor to moderate, most involved domestic class products and one involved occupational (applicator) exposure. The most common effects reported were skin irritation and respiratory irritation. No information was available on whether the products were used according to label directions.

There were four incidents reported for animals for products containing sulphur in Canada and one in the United States of which two were classified as minor, one as moderate and one as death. All incidents involved dogs, most appeared to be the result of accidental ingestion, and four involved products containing other active ingredients in addition to sulphur. The most common symptoms reported were gastrointestinal effects (i.e., vomiting, anorexia, diarrhea) and lethargy. In the one U.S. incident, severe gastrointestinal effects and death were reported, but based on the available information, ingestion of the product was not suspected as the cause of death.

The PMRA concluded that the information from the incident reports supported the current toxicity database for sulphur; however, it did not impact upon the risk assessment for Grotek Ascend Vaporized Sulphur. Further information on the incidents can be found on the PMRA Public Registry.

5.0 Impact on the Environment

5.1 Fate and Behaviour in the Environment

The end-use product consists of elemental sulphur, so no breakdown will occur once released into the environment. The product is applied as a vapour within the enclosed space of a greenhouse, and ultimately vented to the outside in a controlled manner once treatment is completed; the only contact sulphur will have with the environment is at the point of venting. Assuming all applied product is vented to the outside, a maximum of 320 g sulphur per application will be released over a hypothetical greenhouse venting area of one hectare (i.e., at a maximum application rate of 320 g per hectare). This relatively small amount per unit area is expected to dissipate rapidly in the air upon release, and cause minimal environmental exposure.

5.2 Effects on Non-Target Species and Environmental Risk Characterization

When the generation of quantitative data are not practical or apparent risks are considered minimal, a qualitative assessment may be more appropriate. This is considered in the case of

non-conventional pest control products, as defined in PRO2010-06 - Guidelines for the Registration of Non-Conventional Pest Control Products.

In this case, a qualitative environmental risk assessment was conducted for sulphur and the associated end-use product Grotek Ascend Vaporized Sulphur. In the original pre-submission consultation for this product, the environmentally-related information requested pertained to the potential effects of vaporized sulphur on non-target arthropods. As part of the current applications, the applicant has submitted information pertaining to the potential effects of vaporized sulphur on non-target arthropods in the form of a summary of pertinent literature. The applicant concluded that vaporized sulphur will be toxic to non-target arthropods, such as those used in greenhouses for biological control programs. The applicant maintains that this information is well-known to the industry, and expertise is in place to manage these effects. The applicant also suggests that these effects should be stated on the label, and has provided suggested label statements in this regard. In addition, although no data were provided by the applicant, the potential effects of vaporized sulphur on birds in the vicinity of the vented product were also considered as part of the qualitative risk assessment.

The environmentally-related information provided by the applicant for these submissions was acceptable. The applicant provided an accurate summary of literature that indicates sulphur is toxic to beneficial arthropods used in greenhouse environments as part of integrated pest management (IPM). Sulphur is already registered for greenhouse uses as a spray application, and on these already registered products any implications towards IPM practices in greenhouses have been addressed by the industry. The use of sulphur as a vapour is not expected to result in any additional environmentally-related concerns, and mitigative IPM-related label statements will be put on the label.

Based on the fact that the product is used in an enclosed space and that the only environmental exposure would be at the point of venting, limited environmental exposure is expected. Potential effects on non-target arthropods and birds in the vicinity of venting would be minimal, since a low amount of sulphur would be released at any given time, and done so over an extended period of up to six hours where rapid dissipation in air would occur once outside.

6.0 Value

6.1 Effectiveness Against Pests

6.1.1 Acceptable Efficacy Claims

6.1.1.1 Control of powdery mildew (*Oidium lycopersicum*) on greenhouse tomato

Bartlett Microscopic Sulphur (*Pest Control Products Act* Registration number 873) is currently registered for the use on tomato. The results from one trial conducted in the Netherlands, using the proposed product, demonstrated both vaporized sulphur and scattering sulphur on the ground controlled powdery mildew on tomato. Use history information from the Netherlands was

considered. The claim is supported at the proposed rate (1 unit/1,000 m^2, runs 1-8 hr/night and 2-7 night/wk).

6.1.1.2 Control of powdery mildew (*Leveillula taurica*) on greenhouse pepper and eggplant

Use history on greenhouse pepper from the Netherlands was considered. Eggplant is a member of the Solanaceae family, which includes tomato and pepper. Powdery mildew on eggplant is caused by the same pathogen as on pepper. Therefore, the use on tomato and pepper can be extrapolated to support the use on greenhouse eggplant. The claim is supported at the proposed rate (1 unit/1,000 m^2, runs 1-8 hr/night and 2-7 night/wk).

6.1.1.3 Control of powdery mildew (*Sphaerotheca macularis*) on greenhouse strawberry

No efficacy data or use history information were provided for this use. However, Green Earth Garden Sulphur (*Pest Control Products Act* Registration number 21890, containing 92% sulphur) and four other sulphur products (containing 0.4 -12% sulphur) are currently registered for the control of powdery mildew on strawberry by either spray or dust applications. The claim is supported at the proposed rate (1 unit/1,000 m^2, runs 1-8 hr/night and 2-7 night/wk).

6.1.1.4 Control of powdery mildew (*Sphaerotheca pannosa*) on greenhouse ornamentals (rose)

There are currently ten sulphur products registered for the control of powdery mildew on rose by either spray or dust applications. Use history information from the Netherlands was considered. The claim is supported at the proposed rate (1 unit/100 m^2, runs 1-8 hr/night and 2-7 night/wk).

6.1.1.5 Control of powdery mildew (*Erysiphe cichoracearum, E. polygoni*) on greenhouse ornamentals (African violet, begonia, Chrysanthemum, dahlia, gerbera, hydrangea, kalanchoe, phlox and snapdragon)

There are currently ten sulphur products registered for the control of powdery mildew on flowers, chrysanthemum and dahlia by either spray or dust applications. Use history information from the Netherlands was considered. The two *Erysiphe* species (*E. cichoracearum* and *E. polygoni*) most commonly seen on many ornamental plants in greenhouse can be supported based on extrapolation from the currently registered uses. The claim is supported for *Erysiphe cichoracearum* and *E. polygoni* at the modified rate (1 unit/250-1,000 m^2, runs 1-8 hr/night and 2-7 night/wk).

6.2 Phytotoxicity to Host Plants

Currently registered labels for sulphur products indicate that there is potential phytotoxicity when sulphur products are applied under high temperature (over 24 °C) and high humidity. Sulphur phytotoxicity can be related to sulphur particle size. Particles less than 1µm are absorbed into stomata where they can cause phytotoxicity. It is possible that vaporized sulphur may cause phytotoxic reactions under similar conditions. In order to mitigate potential

phytotoxicity, a label statement that recommends testing of a small number of plants is being added to the label.

6.3 Economics

No market analysis was done for this application.

6.4 Sustainability

6.4.1 Survey of Alternatives

Refer to Appendix I, Table 1 for a summary of the active ingredients currently registered for the same uses as Grotek Ascend Vaporized Sulphur.

6.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

The use of Grotek Ascend Vaporized Sulphur is compatible with current integrated pest management practices and production practices.

6.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Grotek Ascend Vaporized Sulphur contains sulphur, a Group M2 fungicide, which is generally considered at low risk of disease resistance development according to the Fungicide Resistance Action Committee (FRAC). To date, there have been no reports of resistance to this active ingredient. Statements that will contribute to managing disease resistance will be added to the label.

6.4.4 Contribution to Risk Reduction and Sustainability

Grotek Ascend Vaporized Sulphur offers Canadian greenhouse growers an additional application method of sulphur to control powdery mildew in greenhouse.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, elemental sulphur was considered in accordance with the PMRA Regulatory Directive DIR99-03[5]. The PMRA has reached the following conclusions:

- Elemental sulphur is not a concern with regard to the Track 1 criteria. As sulphur is elemental, it will not form any transformation products and, therefore, would not meet the Track 1 criteria.

7.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use product are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade sulphur, and the end-use product Grotek Ascend Vaporized Sulphur do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[9].

8.0 Summary

8.1 Human Health and Safety

The available toxicological information and reviews are sufficient to identify the potential risks

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

8 DIR2006-02, PMRA Formulants Policy.

9 DIR2006-02, PMRA Formulants Policy.

associated with exposure to vaporized sulphur and any sulphur dioxide formed during the vaporization process. Sulphur is of low acute toxicity by the oral, dermal, and inhalation routes. Sulphur is also considered to be a mild skin irritant, moderately irritating to the eyes, and non-sensitizing. The end-use product, Grotek Ascend Vaporized Sulphur, contains no formulants of toxicological concern.

Sulphur is a natural component of all cells, it is of low toxicity, and residues of vaporized sulphur should not result in additional exposure beyond currently registered food uses of sulphur. Consequently, exposures to food residues of vaporized sulphur are not of concern and a MRL is not required.

The toxicity of sulphur is low by the dermal and inhalation routes of exposure. Workers filling and servicing sulphur vaporizers are expected to be exposed to similar or lesser amounts of sulphur compared to workers handling currently registered products containing sulphur. These workers are also required to wear similar PPE as workers handling currently registered products. Sulphur vaporizers are to be operated by a timer or remote switch and greenhouse entrances should be locked and have warning signs during vaporization. Workers are not to enter the greenhouse until vaporization is complete, the greenhouse is thoroughly ventilated, and the re-entry interval on the label has passed, unless they are wearing protective clothing and a self-contained breathing apparatus. Because the application rates for Grotek Ascend Vaporized Sulphur are lower than application rates for currently registered products containing sulphur, workers performing crop maintenance and harvesting tasks are expected to be exposed to smaller amounts of sulphur than workers performing similar tasks for crops treated with currently registered products. As a result, occupational exposures to sulphur during filling and servicing vaporizers, vaporization of the end use product, and crop maintenance and harvesting tasks are not of concern.

Sulphur dioxide can be formed if sulphur is (over-)heated beyond vaporization temperatures. Precautionary statements on the label for Grotek Ascend Vaporized Sulphur include instructions for avoiding the formation of sulphur dioxide when filling of the vaporizers and the estimated levels of sulphur dioxide formed during vaporization are less than occupational exposure limits included in provincial occupational health and safety regulations.

Grotek Ascend Vaporized Sulphur is not intended for use in residential or non-occupational environments and the label for the product includes directions for preventing bystander or non-occupational exposure to vaporized sulphur. Therefore, residential or non-occupational exposures to vaporized sulphur via the dermal or inhalation routes are not of concern.

8.2 Environmental Risk

Sulphur is expected to dissipate rapidly once vented into the environment. The product has potential to be toxic to non-target arthropods, such as those used for IPM purposes in greenhouses. Mitigative statements in this regard have been developed and will be put on the current label. When used under the registered use pattern within greenhouses, the product is expected to pose a minimal risk to non-target organisms.

Since the product is not expected to build-up in the environment under the current use pattern, and exposure to non-target organisms is expected to be low, risk to the environment through this use will be minimal, and is acceptable.

8.3 Value

Value evidence was provided to support the use of Grotek Ascend Vaporized Sulphur to control powdery mildew on greenhouse vegetables, small fruit (strawberry), and greenhouse ornamentals. Grotek Ascend Vaporized Sulphur offers Canadian greenhouse growers an additional application method of sulphur to control powdery mildew on various crops and plants listed above in greenhouse.

A summary of the proposed and accepted uses for Grotek Ascend Vaporized Sulphur is presented in Appendix I, Table 2.

9.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Hollysul Technical Sulphur and Grotek Ascend Vaporized Sulphur, containing the technical grade active ingredient sulphur, to control powdery mildew caused by various pathogens on greenhouse vegetables, small fruit, and greenhouse ornamentals in greenhouses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µm	micrometres
CAS	Chemical Abstracts Service
cm	centimetres
FRAC	Fungicide Resistance Action Committee
g	gram
hr	hour(s)
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*–octanol-water partition coefficient
L	litre
m	metre(s)
mg	milligram
mL	millilitre
mPa	millipascals
MRL	maximum residue limit
nm	nanometres
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
REI	restricted entry interval
TSMP	Toxic Substances Management Policy
U.S.	United States
USC	use site category
UV	ultraviolet
wk	week

Appendix I Tables and Figures

Table 1 Summary of Alternatives for the Same Uses as Grotek Ascend Vaporized Sulphur

Crop	Disease	Active ingredient and FRAC Fungicide Group
Greenhouse tomato	Powdery mildew (*Oidium lycopersicum*)	Boscalid (7) + Pyraclostrobin (11) (Suppression) Garlic (Biological, suppression) Myclobutanil (3) Potassium bicarbonate (NC) Sulphur (M2)
Greenhouse pepper	Powdery mildew (*Leveillula taurica*)	*Bacillus subtilis* (44) (Suppression) Boscalid (7) + Pyraclostrobin (11) Myclobutanil (3) Potassium bicarbonate (NC) *Streptomyces lydicus* (Biological, suppression) Sulphur (M2)
Greenhouse eggplant	Powdery mildew (*Leveillula taurica*)	N/A
Greenhouse strawberry	Powdery mildew (*Sphaerotheca macularis*)	Boscalid (7) + Pyraclostrobin (11) Myclobutanil (3) Quinoxyfen (13) *Streptomyces lydicus* (Biological, suppression)
Greenhouse rose	Powdery mildew (*Sphaerotheca pannosa*)	*Bacillus subtilis* (44) (Suppression) Copper (M1) Dodemorph-acetate (5) Folpet (M4) Myclobutanil (3) Propiconazole (3) Sulphur (M2) Thiophanate-methyl (1)
Greenhouse ornamentals	Powdery mildew (*Erysiphe cichoracearum, Erysiphe polygoni*)	*Bacillus subtilis* (44) (Suppression) Chlorothalonil (M5) Copper (M1) Boscalid (7) + Pyraclostrobin (11) Folpet (M4) Myclobutanil (3) Potassium bicarbonate (NC) Propiconazole (3) *Streptomyces lydicus* (Biological, suppression) Sulphur (M2) Thiophanate-methyl (1) Trifloxystrobin (11) (Suppression)

Table 2 Use (label) Claims Proposed by Applicant and Accepted

Proposed claim	Accepted claim
1) Control of powdery mildew (*Oidium lycopersicum*) on greenhouse tomato using one (1) vaporizer per 1,000 m^2 in the greenhouse.	As proposed.
2) Control of powdery mildew (*Leveillula taurica*) on greenhouse pepper and eggplant using one (1) vaporizer per 1,000 m^2 in the greenhouse.	As proposed.
3) Control of powdery mildew (*Sphaerotheca macularis*) on greenhouse strawberry using one (1) vaporizer per 1,000 m^2 in the greenhouse.	As proposed.
4) Control of powdery mildew (*Sphaerotheca pannosa*) on greenhouse rose using one (1) vaporizer per 100 m^2 in the greenhouse.	As proposed.
5) Control of powdery mildew (*Erysiphe cichoracearum, Erysiphe polygoni, Microsphaera begoniae, Microsphaera* spp., *Oidium begoniae, Oidium chrysanthemi, Oidium* spp., *Podosphaera fusca, Sphaerotheca fuginea*) on greenhouse ornamentals using one (1) vaporizer per 350 - 500, 200, 250, or 250 - 1,000 m^2 in the greenhouse.	Accepted for two common causal pathogens *Erysiphe cichoracearum* and *Erysiphe polygoni* using one (1) vaporizer per 250 - 1,000 m^2 in the greenhouse.

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A. List of Studies/Information Submitted by Registrant

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2.0 Human and Animal Health

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1952649 Adverse Effects on Use Site , DACO: 10.3

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2090582 Koppert Biological Systems – Use of sulphur burners in Dutch Horticulture, DACO: 10.6

2090585 Hotbox International - Sulfume Sulphur Vaporizer, DACO: 10.6

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2090589 More about Sulphur Evaporation, DACO: 10.6

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2090596 Dutch Use History Summary, DACO: 10.7.2

3.0 Environment

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3.0 Value

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ii) Unpublished Information

1.0 Human and Animal Health

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